DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 - 2005

Ms. Kim Reed
Senior Regulatory Specialist
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K040983
Trade/Device Name: Lorenz Self-Drilling IMF Screws
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 13, 2004
Received: April 15, 2004

Dear Ms. Reed:

This letter corrects our substantially equivalent letter of April 15, 2004 regarding the incorrect product code of Lorenz Self-Drilling IMF Screws.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K040983

TAB 2 – Summary of Safety and Effectiveness

510(k) Summary (per 21 CFR 807.92(c))

SUBMITTER

Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218
FDA Registration No. 1032347

MAY - 5 2004

PRODUCT NAME

Common/Usual Name: Bone Screw
Proprietary Name: Lorenz Self-Drilling IMF Screw

DEVICE CLASSIFICATION

The FDA has cleared radiographic markers via 510(k) Premarket Notification as Product Code DZL and Classification number 872.4880 Screw, Fixation, Intra osseous - Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for implantable radiographic markers.

PREDICATE DEVICE

The predicate device is the Lorenz IMF Screw cleared under W. Lorenz 510(k) number K983728 on May 13, 1999.

DESCRIPTION OF DEVICE

The Self-drilling IMF bone screw for maxillomandibular fixation is 2.0mm in diameter and the thread lengths may range from 5mm – 11mm. The head has a relief groove which may or may not have a hole in which wire or elastic bands can be wrapped around the screws which are temporarily implanted in the maxilla and mandible.

INTENDED USE OF THE DEVICE

The Lorenz Self-Drilling IMF Screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.

STATEMENT OF COMPARISON OF TECHNOLOGICAL FEATURES

Both the new and the old devices consist of non absorbable material (titanium) listed in FDA's Biomaterials Compendium and list of FDA recognized standards. Both the predicate devices and the modified devices are implanted into bone during surgical procedures to provide temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible. The metallic materials and intended use are technically equivalent.

CONCLUSIONS

The use of modified IMF screws and the predicate IMF screws is substantially similar.

Indications for Use

510(k) Number (if known): K040983

Device Name: Lorenz Self-Drilling IMF Screws

Indications for Use:

The Lorenz Self-Drilling IMF Screw is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040983

(Posted November 13, 2003)